

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : Annapragada et al.
Application No. : 10/830,190
Filing Date : April 21, 2004
Examiner : Perreira, Melissa Jean
Art Unit : 1618
Docket No. : 27428-4
Title : Compositions and Methods for Enhancing Contrast in Imaging

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

INTERVIEW SUMMARY RECORD UNDER M.P.E.P. § 713.04

In response to the September 13, 2007 Office Action issued in connection with the above-referenced patent application ("subject application"), Applicants hereby submit a complete and proper recordation of the substance of the telephonic interview conducted on September 7, 2007.

The Office Action set a shortened statutory period for response of one month to expire on October 13, 2007. This Interview Summary Record under M.P.E.P. § 713.04 is being filed on September 18, 2007 via the USPTO Electronic Filing System. Thus, this Response is timely filed.

REMARKS

Applicants again wish to thank the Examiner for the consideration given to this case to date. The telephonic interview kindly granted by the Examiner on September 7, 2007 is particularly acknowledged and appreciated. The participants to the interview were the Examiner and the attorney for Applicants, Benjamin E. Kern ("Applicants' counsel"). No other USPTO personnel participated in the telephonic interview.

In accordance with M.P.E.P. § 713.04, a complete and proper recordation of the substance of the September 7, 2007 telephonic interview is as follows:

(A) A brief description of the nature of any exhibit shown or any demonstration conducted.

No exhibits were shown and no demonstrations were conducted during the interview.

(B) Identification of the claims discussed.

The participants particularly discussed pending claims 1, 25, 31, and 33 of the subject application, but also generally discussed the Examiner's concerns about all of the pending claims.

(C) Identification of specific art discussed.

The participants discussed Leike et al, Invest. Radiol. 2001, 36, 303-308 ("Leike"), Torchilin et al., Biochim. Biophys. Acta 1996, 1279, 75-83 ("Torchilin"), Sachse et al., Invest. Radiol. 1997, 32, 44-50 ("Sachse"), U.S. Patent No. 6,217,849B1 issued to Tournier et al. ("Tournier"), and, to a lesser extent, U.S. Patent No. 5,676,928 issued to Klaveness et al.

(D) Identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary form completed by the examiner.

The following principal proposed amendments of a substantive nature were discussed:

(1) The amendment to claim 33 to exclude the percentages of the constituents and, thus, remove the 112 rejection;

(2) The amendment to claim 31 to eliminate the recitation of "essentially free" and, thus, remove the 112 rejection;

(3) The amendment to claims 1 and 25 to eliminate the term "about";

(4) The Examiner suggested that Applicants include a specific iodinated compound;

(5) The amendment to claim 1 to designate cholesterol as the pharmaceutically acceptable excipient; and

(6) The amendment to claims 1 and 25 to clarify that the nonradioactive contrast enhancing agent called for in those claims is encapsulated in the sterically stabilized liposomes.

(E) The general thrust of the principal arguments of the applicant and the examiner should also be identified, even where the interview is initiated by the examiner. The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.

Applicants' counsel asserted that the combination of Leike (liposome size = 201 nm) and Sachse (liposome size = 204 nm) does not teach each and every element of amended claims 1 and 25. In particular, the combination of Leike and Sachse does not teach sterically stabilized liposomes have a size of less than 150 nm.

Applicants' counsel also asserted that Torchilin teaches the preparation of liposomes from a mixture of PC, cholesterol, PEG-PE, and DTPA. The Torchilin compositions and the claimed compositions are clearly distinct because the introduction of the radioactive tracer in Torchilin, In^{111} , is made possible through chelation—that is, attachment to the outside of the liposomes—via DTPA. As a result, Torchilin is able to maintain the small liposome sizes (i.e., 120-150 nm). In contrast, the claimed compositions contain nonradioactive contrast enhancing agent encapsulated in the sterically stabilized liposomes, while maintaining the small size.

Applicants' counsel also referenced the clear teaching away by Tournier of small, PEGylated liposomes for imaging purposes. Applicants' counsel further asserted that Tournier does not disclose liposomes of 100 nm for imaging purposes, and certainly does not disclose PEGylated liposomes of 100 nm, but merely offers a demonstrative calculation to show the impracticability of 100 nm vesicles having 100 mg/ml of iodine.

(F) A general indication of any other pertinent matters discussed.

No other pertinent matters were discussed.

(G) If appropriate, the general results or outcome of the interview unless already described in the Interview Summary form completed by the examiner.

The Examiner agreed to consider arguments and/or claim amendments, but suggested the filing of a request for continued examination.

(H) In the case of an interview via electronic mail, a paper copy of the Internet e-mail contents MUST be made and placed in the patent application file as required by the Federal Records Act in the same manner as an Examiner Interview Summary Form, PTOL 413, is entered.

Not applicable.

CONCLUSION

No fees are believed due in relation to this Response. If additional fees are believed due, the Commissioner is hereby authorized to charge the additional fees, or credit any overpayment, to Deposit Account No. 02-2051, referencing Attorney Docket No. 27428-4.

Respectfully submitted,

Dated: September 18, 2007

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